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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,281	08/22/2006	Lucio Filippini	163-711	8075
7590 James V. Costigan Hedman & Costigan 1185 Avenue of the Americas New York, NY 10036-2646	06/09/2009		EXAMINER RICCI, CRAIG D	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 06/09/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/590,281	FILIPPINI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	CRAIG RICCI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 March 2009.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-8 and 10-21 is/are pending in the application.  
 4a) Of the above claim(s) 5,7,8 and 13-21 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-4,6 and 10-12 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>3/31/2009</u> .	6) <input type="checkbox"/> Other: _____ .

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I in the reply filed on 12/10/2008 is acknowledged. Applicant argues that there exists a technical relationship between the separately grouped claims in that they are chemical compounds and compositions of the chemical compounds and methods of using the chemical compounds. Yet, as discussed in the Requirement for Restriction mailed on 11/13/2008, Dean (WO 2000/005954) teaches a composition comprising salicylic acid and an organic amine (i.e., a PRO compound) as recited by instant claim 1. As such, the technical feature is not a special technical feature, and unity between the groups is broken. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. Applicant further elected the composition comprising (A) a copper (II) salt of acetylsalicylic acid wherein the acid/copper ratio is equal to 2:1 on 12/10/2008 and (B) titanium dioxide as a PRO compound in micronized form on 03/27/2009 wherein no MOD compound is present, no active principles are further present, and the compounds are not present in the hydrate form. The elected species read upon claims 1-4, 6 and 10-12. Claims 5, 7-8 and 13-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/10/2008.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 3-4, 6 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

6. Instant claim 3 (from which claim 4 depends) is drawn to a compound having the formula (I). However, there is no formula (I) present. Accordingly, it is unclear what is meant by a compound having a formula (I) and one of ordinary skill in the art would not reasonably be able to ascertain the scope of the claims. For this reason, claims 3 and 4 are rejected as indefinite.

7. Regarding instant claims 6 and 12, I it is not clear whether the phrases "such as" (in claim 6) and "preferably" (in claim 12) is a limitation or whether it is merely listing disclosed examples and/or embodiments. Description of examples or preferences is properly set forth in the specification rather than the claims. Since it is unclear whether this phrase is a limitation, and thus part of the claimed invention, this phrase renders the claim indefinite.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 1-4, 6, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Cowie* (US 5,599,529), *Sorenson* (US 4,657,928), *Miyachi et al* (Clin Exp Dermatol 8:305-310, 1983) and *Greene et al* (WO 1999/33439).**

11. Instant claim 1 is drawn to a blend comprising two or more compounds wherein Applicant has elected (A) the copper salt of acetylsalicylic acid and (B) micronized titanium dioxide, which reads on claims 1-4, 6, 10 and 12. More specifically, as recited by instant claim 11, the particles of the micronized titanium dioxide have a particle size lower than 1 micron. Thus, as discussed above, the elected invention reads on instant claims 1-4, 6 and 10-12.

12. Compositions, such as sunscreens, comprising micronized titanium dioxide having a particle size lower than 1 micron are well known in the art and are specifically taught, for example, by *Cowie* (US 5,599,529) (Column 1, Lines 10-12, and Column 1, Lines 35-37). However, *Cowie* does not teach a blend which also comprises copper acetylsalicylic acid as recited by the instant claims.

13. *Sorenson* (US 4,657,928) discloses that organic copper complexes and especially copper (II) acetylsalicylic acid (Column 4, Lines 65-68) exhibits superoxide dismutase activity, acts as a superoxide scavenger and is useful as a radioprotectant (Abstract) which can be administered topically (Column 3, Lines 59). Although *Sorenson* does not teach copper (II) acetylsalicylic

acid for use in a sunscreen, *Miyachi et al* teach that sunburn cell formation is prevented by scavenging oxygen intermediates such as superoxide using superoxide dismutase (Abstract; Page 307, Figure 1). Furthermore, it is well known in the art, and specifically taught by *Greene et al* (WO 1999/33439) that sunscreen formulations comprising superoxide dismutase as an antioxidant protect the skin from UV radiation (Page 6, Lines 3-18). Thus, although *Sorenson* does not teach copper (II) acetylsalicylic acid for use in a sunscreen, the skilled artisan, in view of *Sorenson*, would have recognized that copper (II) acetylsalicylic acid exhibits superoxide dismutase activity, acts as a superoxide scavenger and is useful as a radioprotectant, and would have reasonably predicted that copper (II) acetylsalicylic acid would protect the skin against UV damage similar to superoxide dismutase as taught by *Miyachi et al* and *Greene et al*. Accordingly, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to formulate a sunscreen comprising copper (II) acetylsalicylic acid in view of *Miyachi et al* with a reasonable expectation of success. In particular, the skilled artisan would have found it *prima facie* obvious to substitute copper (II) acetylsalicylic acid as taught by *Sorenson* in place of in place of superoxide dismutase in the sunscreen formulation taught by *Greene et al*. The simple substitution of one known antioxidant (i.e., superoxide dismutase) with another (i.e., copper (II) acetylsalicylic acid having superoxide dismutase activity) according to known methods to provide predictable results is *prima facie* obvious.

14. Furthermore, it would have been *prima facie* obvious to formulate a sunscreen comprising micronized titanium dioxide and copper (II) acetylsalicylic acid in view of *In re Kerhoven*, 626 F.2d 846 (CCPA 1980). As stated in MPEP 2144.06, “It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same

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purpose, in order to form a third composition to be used for the very same purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846 (CCPA 1980). Thus, in the instant case, it would have been *prima facie* obvious to combine micronized titanium dioxide and copper (II) acetylsalicylic acid, both of which are taught as useful in sunscreen formulations, to form a third composition to be used for the very same purpose.

15. Accordingly, instant claims 1-4, 6 and 10-12 are rejected as *prima facie* obvious.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/  
Examiner, Art Unit 1614

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614